

expressly reserve the right to file one or more dependent claims directed to the second and third identified species upon the allowance of a generic claim. Furthermore, Applicants expressly reserve the right to file one or more divisional or other continuing applications to protect the inventions of the second and third identified species and other disclosed, but unclaimed, subject matter prior to the issuance of this application, if necessary.

Claim Rejections- 35 U.S.C. § 112

The Examiner rejected claim 19 under the second paragraph of 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner asserted that there is an inconsistency between the language of the preamble and the scope of the claim. In response, claim 19 has been amended to eliminate any positive recitation of the implant. In light of this claim amendment, Applicants respectfully submit that the indefiniteness rejection has been overcome.

Claim Rejections- 35 U.S.C. § 102

Russian Publication No. 2008851

Claims 1, 4-6, 9, 12, and 14-16 were rejected under 35 U.S.C. § 102(b) as being anticipated by Russian Publication No. 2008851 (the “Russian ‘851 publication”). Applicants respectfully disagree. Claim 1 as originally filed specified that the end member includes “a shoulder joining the first and second portions and sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant.” The Russian ‘851 publication does not teach or suggest any shoulder as claimed. In the rejection, the Examiner did not identify any shoulder between the components construed as first and second portions. As the Russian device is an implant that can only be coupled to other implants with fixing elements in such a way that there is no contact between the two implants, the Russian ‘851 publication does not teach or suggest any structure that rests on an edge of a second implant. Furthermore, claim 1 as originally filed specified that the second portion is “configured and dimensioned to be inserted in a bore of the implant.” As was the case for the claimed shoulder, the Examiner did not identify any structure in the Russian ‘851 publication that is inserted into a bore.

As the features recited in claim 1 are not taught or suggested by the Russian '851 publication, Applicants submit that this claim is now allowable over the cited reference. With respect to claims 4-6, 9, 12, 14-16, and 24, which depend from claim 1, Applicants submit that, because these claims define more particular aspects of Applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over the Russian '851 publication for the above reasons, as well as the totality of the claimed invention.

U.S. Patent No. 5,702,451 to Biedermann *et al.*

Claims 1, 2, 4-8, 10, 11, 13-15, and 17 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,702,451 to Biedermann *et al.* (the "Biedermann '451 patent"). Once again, the Examiner has not identified any structure in the Biedermann '451 patent that teaches or suggests the shoulder of claim 1. Furthermore, the end member according to the present invention has a first channel for receiving a surgical instrument. The Examiner asserts that holes 14 can be construed as a channel. Applicants respectfully disagree. As shown and described in the instant application, the claimed channel is a longitudinal groove for receiving a surgical instrument. The applicable dictionary definition of "channel" is a furrow, trench, or groove. The American Heritage College Dictionary (3^d Ed.). The holes of the Biedermann '451 patent are simply circular in shape and merely provide access to the underside of the space holder. In addition, the Biedermann holes are centrally located on the plate. In contrast, the channel of the end member according to the present invention extends from the edge of the top surface. In order to clarify this, claim 1 has been amended to specify that the first channel extends from the edge of the top surface.

The Examiner also asserts that prongs 21 "have channels established anterolaterally between the prongs." In support, the Examiner has provided Attachment A showing Figure 9 of the Biedermann '451 patent with "top of prongs" labeled. Applicants respectfully disagree with this characterization. The Biedermann '451 patent states that "FIG. 8 shows a section along line VIII-VIII in FIG. 9." As Figure 8 clearly shows that the prongs do not extend above ring 12 and are not located on any top surface, there can be no channel on the top surface as stated in claim 1. Additionally, the prongs 21 are inserted into recesses 9, 10, 9',

10' of jacket 1 so that any space between the prongs is contained within the jacket and cannot be used to receive a surgical instrument.

As the features recited in claim 1 are not taught or suggested by the Biedermann '451 patent, Applicants submit that this claim is now allowable over the cited reference. With respect to claims 4-8, 10, 11, 13-15, 17, and 24, which depend from claim 1, Applicants submit that, because these claims define more particular aspects of Applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over the Biedermann '451 patent for the above reasons, as well as the totality of the claimed invention.

Claim 2 has been rewritten in independent form to include the elements of claim 1 and now recites that the teeth are provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone. As the prongs of the Biedermann '451 patent form a single ring and not a two dimensional array, Applicants submit that claim 2 is patentable over this reference for this additional reason.

U.S. Patent No. 5,980,522 to Koros *et al.*

Claims 1, 4, 6, 9, 14, and 19 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,980,522 to Koros *et al.* (the "Koros '522 patent"). As was the case for the first two cited references, the Examiner has not identified any structure in the Koros '522 patent that teaches or suggests the shoulder of claim 1. Furthermore, the end member of claim 1 specifies that the top surface of the first portion is adopted and configured to engage the bone. In contrast, the Koros '522 patent teaches a dowel type implant so that the top surface identified by the Examiner does not contact bone, as shown in Figure 1. As previously noted, the first channel of the present invention as shown and described (and in accordance with the dictionary definition), is a longitudinal structure so that holes 145, 146, which are centrally located on the top surface, cannot read upon the first channel of claim 1. In order to clarify this, claim 1 has been amended to specify that the first channel extends from the edge of the top surface.

As the features recited in claim 1 are not taught or suggested by the Koros '522 patent, Applicants submit that this claim is now allowable over the cited reference. With respect to claims 4, 6, 9, 14, 19, and 24, which depend from claim 1, Applicants submit that, because these claims define more particular aspects of Applicants' invention (as well as including the

features of claim 1), they are also patentably distinguished over the Koros '522 patent for the above reasons, as well as the totality of the claimed invention.

U.S. Patent No. 5,776,197 to Rabbe *et al.*

Claims 1-5, 8, 12, 14, and 21 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,776,197 to Rabbe *et al.* (the "Rabbe '197 patent"). As was the case for the previously cited references, the Examiner has not identified any structure in the Rabbe '197 patent that teaches or suggests the shoulder of claim 1. Furthermore, the end member of claim 1 specifies that the second portion is configured and dimensioned to be inserted into a bore of the implant with the shoulder sized to rest on an edge of the implant. In contrast, the second portion of the Rabbe '197 patent identified by the Examiner has an annular surface that is threaded so that threaded cylindrical body 21 is threadably received in the annular surface. This is exactly the opposite of the claimed end member. Thus, the Rabbe '197 patent teaches away from the claimed invention.

As the features recited in claim 1 are not taught or suggested by the Rabbe '197 patent, Applicants submit that this claim is now allowable over the cited reference. With respect to claims 4, 5, 8, 12, 14, 21, and 24, which depend from claim 1, Applicants submit that, because these claims define more particular aspects of Applicants' invention (as well as including the features of claim 1), they are also patentably distinguished over the Rabbe '197 patent for the above reasons, as well as the totality of the claimed invention.

With respect to claims 2 and 3, claim 2 has been rewritten in independent form to include the elements of claim 1 and now recites that the teeth are provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone. Claim 3 remains dependent upon claim 2. As the teeth of the Rabbe '197 patent form a single ring and not a two dimensional array, Applicants submit that claim 2 is patentable over this reference for this additional reason. Applicants respectfully disagree with the characterization of the Rabbe '197 patent teeth as pyramid-shaped. The Rabbe '197 patent is absolutely silent as to the shape of spikes 120. Figure 3 clearly shows that the spikes are conical in shape – not pyramid shape as specified in claim 3. Thus, claim 3 is patentable over the Rabbe '197 for this additional reason.

U.S. Patent No. 5,989,289 to Coates *et al.*

Claims 1-3, 7, 8, 12, and 20 were rejected under 35 U.S.C. § 102(a) as being anticipated by U.S. Patent No. 5,989,289 to Coates *et al.* (the “Coates ‘289 patent”). As was the case for the previously cited references, the Examiner has not identified any structure in the Coates ‘289 patent that teaches or suggests the shoulder of claim 1. Furthermore, the implant taught by the Coates ‘289 patent is a stand-alone implant that is not used in combination with any other implant. As a result, the second portion of the claimed end member, which is inserted into a bore of an implant, and the shoulder of the claimed end member, which rests on an edge of the implant, are not taught or suggested by the Coates ‘289 patent.

As the features recited in claim 1 are not taught or suggested by the Coates ‘289 patent, Applicants submit that this claim is now allowable over the cited reference. With respect to claims 7, 8, 12, 20, and 24, which depend from claim 1, Applicants submit that, because these claims define more particular aspects of Applicants’ invention (as well as including the features of claim 1), they are also patentably distinguished over the Coates ‘289 patent for the above reasons, as well as the totality of the claimed invention.

With respect to claims 2 and 3, claim 2 has been rewritten in independent form to include the elements of claim 1 and now recites that the teeth are provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone. Claim 3 remains dependent upon claim 2. As the teeth of the Coates ‘289 patent form a single row and not a two dimensional array, Applicants submit that claim 2 is patentable over this reference for this additional reason. Applicants respectfully disagree with the characterization of the Coates ‘289 patent teeth as pyramid-shaped. Other than what is shown in Figure 12, the Coates ‘289 patent is absolutely silent as to the shape of the teeth. Thus, claim 3 is patentable over the Coates ‘289 patent for this additional reason.

Claim Rejections- 35 U.S.C. § 103

Claims 17 and 18 were rejected under 35 U.S.C. § 103 as being unpatentable over the Koros ‘522 patent in view of U.S. Patent No. 5,700,291 to Kuslich *et al.* (the “Kuslich ‘291 patent”). As previously noted, the Koros ‘522 patent fails to teach or suggest all of the features of the end member of claim 1. The Kuslich ‘291 patent does nothing to remedy this

defect. Specifically, the Kuslich '291 patent, like the Koros '522 patent, is directed to a cage implant in which the top surface never contacts bone. Additionally, while the Examiner asserts the end cap of the Kuslich '291 patent includes a plurality of tabs, no such tabs are shown or described in the Kuslich '291 patent. All that Figure 7 shows is an area of reduced diameter and the specification simply states that the end cap can be made of a radiolucent material. Thus, Applicants respectfully submit that claims 17 and 18 are patentable over the Koros '522 patent and the Kuslich '291 patent, either alone or in combination.

Conclusion

In view of the foregoing amendments and remarks, it is believed that all rejections have been overcome and should be withdrawn. Thus, all current claims are submitted to be in condition for allowance, early notice of which would be appreciated. If the Examiner does not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and accelerate the eventual allowance of the claims.

No fee is believed to be due for this submission. Should any fee be required, however, please charge such fee to Pennie & Edmonds LLP Deposit Account No. 16-1150.

Respectfully submitted,

Date March 22, 2001

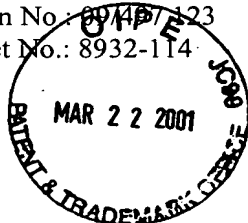


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Enclosure

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Appendix

1. (Amended) An end member for use with an implant for fusing bone comprising:

- a first portion with a top surface [conforming in size and shape with] adopted and configured to engage the bone and having an edge and a first channel extending from the edge for receiving a surgical instrument;
- a second portion configured and dimensioned to be inserted into a bore of the implant;
- and
- a shoulder joining the first and second portions and sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant.

2. (Amended) [The end member of claim 1] An end member for use with an implant for fusing bone comprising:

- a first portion with a top surface adopted and configured to engage the bone and having an edge and a first channel extending from the edge for receiving a surgical instrument;
- a second portion configured and dimensioned to be inserted into a bore of the implant;
- and
- a shoulder joining the first and second portions and sized to rest on an edge of the implant when the second portion is inserted in the bore of the implant,

wherein the top surface further comprises a plurality of teeth provided in a two dimensional array with the teeth being spaced apart from one another for interlocking with the bone.

19. (Amended) The end member of claim 1 wherein the end member is made of [the same material as the implant] a metal.

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